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09/431,607	11/01/1999	LOUIS E. HENDERSON	15280-169300	8955

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EXAMINER

FOLEY, SHANON A

ART UNIT PAPER NUMBER

1648

DATE MAILED: 12/16/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/431,607

Applicant(s)

HENDERSON ET AL.

Examiner

Shanon Foley

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 29 September 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 24-29 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 24-29 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

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### **DETAILED ACTION**

In paper no. 15, applicant amended claims 24 and 25. Claims 24-29 are under consideration.

Previous art rejections regarding DTNB have been obviated by current amendments to the claims. However, if applicant is unable to provide sufficient evidence to support the exclusion of 5,5-Dithiobis(2-Nitrobenzoic Acid) from the claims, the art rejections will be reinstated.

### ***Drawings***

In the response on page 4, applicant references Figure 15. However, it was realized that the application is missing Figures 14 and 15, described on pages 8 and 9. US 6,001,555, parent of this application, depicts the missing figures. Applicant is required to furnish figures 14 and 15 under 37 CFR 1.81 in the instant application. No new matter may be introduced in the required drawings.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 24-29 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant

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art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claims 24 and 25 have been amended to specifically exclude 5,5-Dithiobis(2-Nitrobenzoic Acid). Applicant asserts that this proviso is not new matter and that support for the amendment is located in Figure 15, where it is shown that this compound does not disrupt zinc fingers or inactivate retroviruses.

Although figure 15 is not present in the instant application, the figure was reviewed in the '555 patent. The instant specification was also reviewed. The courts have found that any negative limitation or exclusionary proviso must have basis in the original disclosure. The mere absence of a positive recitation is not basis for an exclusion. See *Ex parte Grasselli*, 231 USPQ 393 (Bd. App. 1983), *aff'd mem.*, 738 F.2d 453 (Fed. Cir. 1984). Page 4, line 1 to page 6, line 1, of the instant disclosure lists compounds asserted to inactivate retroviruses by disrupting CCHC zinc fingers. Page 5, line 22 specifically recites 5,5-Dithiobis(2-Nitrobenzoic Acid) as a disulfide that inactivates retroviruses by the mechanism claimed. There is no data or suggestion in the specification that indicates that this particular disulfide is to be excluded from the family of disulfides having the formula R-S-S-R, recited in line 4 of claim 24. Further, claim 25, before being presently amended, specifically listed this compound. This recitation was a clear assertion that the compound falls within the scope of the claims and metes all of the limitations recited in claim 24. Therefore, this new limitation presented in the claims constitutes new matter. This rejection also affects claims 26-29.

***Claim Rejections - 35 USC § 102***

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 24, 28 and 29 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Levine et al. (WO 92/15329) for reasons of record.

Applicant argues that Levine et al. do not teach inactivation of a mature, active retrovirus, but inhibition of recombinant viral protease. Applicant argues that the instant invention, drawn to inactivating retroviruses by disrupting CCHC zinc finger nucleoproteins, is distinct from the teachings of Levine et al.

Applicant's arguments, declaration and a review of the reference have been considered, but are found unpersuasive. The claims are drawn to composition comprising an inactivated retrovirus that has been inactivated by contact with cupric ions. Levine et al. anticipates an inactivated retrovirus that has been inactivated by a copper ion delivery agent, see the abstract and the claims. Although Levine et al. teach that the copper ions inhibit the HIV protease and does not teach disruption of CCHC zinc finger nucleoproteins, "[t]he claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable." *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977).

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See also MPEP § 2112.01 and § 2141.02. Applicant's inactivated retrovirus, described in product-by process terms, reasonably appears to encompass an inactivated retrovirus that is indistinguishable from the reference's inactivated retrovirus. Therefore, disruption of CCHC zinc fingers would be an inherent property of the copper ions of Levine et al. Therefore, it is maintained that the invention as claimed is prima facie obvious, if not anticipated by the reference.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 24-29 remain rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 6-9 and 25-28 of U.S. Patent No. 6,001,555 for reasons of record. Applicant requests the rejection to be held in abeyance until allowable subject matter is indicated. Until a Terminal Disclaimer is received, the rejection is maintained.

***Requirement for Information***

Applicant and the assignee of this application are required under 37 CFR 1.105 to provide the following information that the examiner has determined is reasonably necessary to the examination of this application.

Claims 24 and 25 have been amended to specifically exclude 5,5-Dithiobis(2-Nitrobenzoic Acid). Applicant argues that DTNB is not commensurate in scope of the claims because the compound does not disrupt zinc fingers in intact retroviruses. Applicant points to figure 15 as evidence to support this conclusion. It appears from figure 15 in the '555 patent that other compounds listed in the claims have the same or similar results observed for DTNB. Therefore, it is not clear which compounds listed in the claims are drawn to non-enabling embodiments. Applicant is required to point out which compounds do not meet the requirements of retroviral activation by the mechanism claimed.

In responding to those requirements that require copies of documents, where the document is a bound text or a single article over 50 pages, the requirement may be met by providing copies of those pages that provide the particular subject matter indicated in the requirement, or where such subject matter is not indicated, the subject matter found in applicant's disclosure.

The fee and certification requirements of 37 CFR 1.97 are waived for those documents submitted in reply to this requirement. This waiver extends only to those documents within the scope of this requirement under 37 CFR 1.105 that are included in the applicant's first complete communication responding to this requirement. Any supplemental replies subsequent to the first communication responding to this requirement and any information disclosures beyond the scope

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of this requirement under 37 CFR 1.105 are subject to the fee and certification requirements of 37 CFR 1.97.

The applicant is reminded that the reply to this requirement must be made with candor and good faith under 37 CFR 1.56. Where the applicant does not have or cannot readily obtain an item of required information, a statement that the item is unknown or cannot be readily obtained will be accepted as a complete reply to the requirement for that item.

A complete reply to the enclosed Office action must include a complete reply to this requirement. The time period for reply to this requirement coincides with the time period for reply to the enclosed Office action.

#### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.




Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shanon Foley whose telephone number is (703) 308-3983. The examiner can normally be reached on M-F 9:30 AM - 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (703) 308-4027. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

  
Shanon Foley

  
JAMES HOUSEL  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600  
12/15/03